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10/553,591	01/17/2006	Surachai Supattapone	DC0258US.NP	6069

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EXAMINER	
BABIC, CHRISTOPHER M	
ART UNIT	PAPER NUMBER
1637	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

poreilly@licataandtyrrell.com

Office Action Summary	Application No.	Applicant(s)	
	10/553,591	SUPATTAPONE ET AL.	
	Examiner	Art Unit	
	CHRISTOPHER M. BABIC	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 August 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6 and 7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6 and 7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Claim(s) 6 and 7 are pending and under examination. The following Office Action is in response to Applicant's communication dated August 18, 2009.

Claim Interpretation

Applicant is advised of the broad nature of the claimed invention. While the term "isolated" does distinguish the claimed biological matter from its natural surroundings or environment, the term "of" is interpreted as open or "comprising" language, which allows for the inclusion of outside elements. Thus, any prior art reference disclosing a product, isolated in any manner from its natural surroundings, that necessarily contains the recited "fraction" would read on the claimed invention.

Response to Remarks

Applicant's remarks are noted. The examiner respectfully disagrees with Applicant's interpretation of the claim language. MPEP 2111.03, under the section "Other Transitional Phrases, clearly recites, "Transitional phrases such as "having" must be interpreted in light of the specification to determine whether open or closed claim language is intended. See, e.g., Lampi Corp. v. American Power Products Inc., 228 F.3d 1365, 1376, 56 USPQ2d 1445, 1453 (Fed. Cir. 2000)." The specification does not define the term "of" as expressly meaning open or closed language. Thus, the term

must be read as allowing for the inclusion of outside elements. MPEP 2111.03 further recites that, " The transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., Ex parte Davis, 80 USPQ 448, 450 (Bd. App. 1948) ("comprising" leaves "the claim open for the inclusion of unspecified ingredients even in major amounts")."

Thus, the rejection is maintained.

Claim Rejections - 35 USC § 112 - Written Description - Maintained

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim(s) 6 and 7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The written description requirement ensures that an applicant invented the subject matter that is claimed. Further, the written description requirement for a claimed

genus may be satisfied through a sufficient description of a representative number of species by 1) reduction to practice; 2) reduction to drawing; or 3) disclosure of relevant identifying characteristics (i.e., structure of other physical and/or chemical properties, functional characteristics coupled with a known or disclosed correlation between function and structure) (see MPEP 2136).

In the instant case, the claimed invention encompass fractions of nucleic acid molecules that are not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed genus. Specifically, the specification provides no support for fractions of strictly polyA- RNA molecules greater than 400, 500, etc. nucleotides that enhance amplification PrP^{Sc}.

Reduction to Practice

The specification discloses that RNA which enhanced PrPSc amplification was determined to be greater than 300 nucleotides (pg. 7); however, there is no evidence that a fraction containing solely polyA- RNA molecules greater (e.g. 400, 500, etc.) nucleotides would enhance PrPSc amplification. Also, the specification provides no experimental evidence of even one molecular sequence structure thought to have "enhancement" properties.

Reduction to Drawing

The specification provides no written sequence structure of even one RNA molecule thought to have "enhancement" properties.

Disclosure of Relevant Identifying Characteristics

While one could argue that a skilled artisan would be able to identify the specific RNA molecules having such "enhancement" properties through "routine" methods known within the art (e.g. SELEX), such methods would not satisfy the written description for the genus claims when the claims require an essential or critical feature(s), adequately described in the specification, when the feature(s) is not conventional in the art or known to one of ordinary skill in the art (MPEP 2163). For the claims at hand, an example of an essential or critical feature is the RNA sequence structure essential for the "enhancement" property. For example, the specification recites, "The RNA molecule may be the entire RNA molecule or an active fragment thereof which retains the capacity for enhancing the amplification of PrP^{Sc} (pg. 10);" however, the sequence of such an active fragment was not elucidated.

Applicant has not disclosed enough number of species within the claimed genus that would indicate a characteristic RNA sequence structure that would permit a person skilled in the art to clearly recognize that Applicant had possession of the genus embraced by the claimed invention.

With specific regard to the amendment of terms "does" to "do" and "enhances" to "enhance," this change creates another description issue. By such a change, it is now the molecules themselves that must possess the ability to enhance amplification of

PrP^{Sc} and not merely the fraction as a whole. Thus, at a minimum the claim encompasses a composition comprising only ribonucleic acid molecules of greater than 300 nucleotides in length that do not bind to an oligo dT column and enhance amplification of PrP^{Sc}. Applicant has not demonstrated possession of such a composition. As understood by the examiner, Applicant has isolated a fraction of molecules which enhance amplification of PrP^{Sc}; however, Applicant has yet to elucidate the actual sequence structure of the specific ribonucleic acid molecules within the fraction itself that are responsible for the amplification. In other words, the disclosure does not describe a composition wherein every single molecule within that composition possesses the claimed characteristics.

In support of the examiner's position, Applicant is directed to *The Regents of the University of California v. Eli Lilly and Co*, 43 USPQ2d 1398 (Fed. Cir. 1997), in which the court found that:

"In claims to genetic material, however, a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA," without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. See *Fiers*, 984 F.2d at 1169- 71, 25 USPQ2d,1605-06 (discussing Amgen). It is only a definition of a useful result rather than a definition of what achieves that result. Many such genes may achieve that result. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736 F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming the rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to

what that material consists of, is not a description of that material. "

Also, in *Fiers v. Revel*, 25 USPQ2d 1601 (Fed. Cir. 1993), the court found that:

"...if inventor is unable to envision detailed chemical structure of DNA sequence coding for specific protein, as well as method of obtaining it, then conception is not achieved until reduction to practice has occurred, that is, until after gene has been isolated...conception of any chemical substance, requires definition of that substance other than by its functional utility."

Thus, for the foregoing reasons, it is the position of the examiner that at the time the application was filed, the claimed subject matter was not sufficiently described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention.

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive.

The examiner interprets the claimed invention to encompass a range of minimum length ribonucleotide molecules. In other words, the invention encompasses a composition wherein the minimum length of ribonucleic acid molecule may be 300, or 301, or 302 nucleotides, and up. As noted above, since Applicant did not elucidate the actual sequence structure of the ribonucleic molecules which enhance amplification of PrP^{Sc}, the claimed invention is not described for such a range of molecules.

Thus, the rejection is maintained.

Claim Rejections - 35 USC § 102 - Maintained

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claim(s) 6 is rejected under 35 U.S.C. 102(b) as being anticipated by Saborio et al. ("Sensitive detection of pathological prion protein by cyclic amplification of protein misfolding" Nature. 2001 Jun 14;411(6839):810-3).

Saborio teaches in vitro amplification of PrP^{Sc} (abstract; fig. 1, PMCA, for example). Specifically, Saborio teaches a composition comprising: a fraction of polyA-RNA molecules greater than 300 nucleotides that enhance the amplification of PrP^{Sc} (fig. 2-3, healthy hamster brain homogenate necessarily "comprises" a fraction of polyA-RNA molecules greater than 300 nucleotides that enhance the amplification of PrP^{Sc}, i.e. Saborio teaches that the conformation of PrP^{C} to PrP^{Sc} is enhanced in the presence of healthy hamster brain homogenate; such inherency naturally flows from the findings of Applicant disclosed on pg. 8, lines 20-end, for example).

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive.

As noted above (see claim interpretation), the examiner interprets the term "of" as open language which allows for the inclusion of outside elements. Thus, the prior art continues to anticipate the claimed invention.

Thus, the rejection is maintained.

2. Claim(s) 6 is rejected under 35 U.S.C. 102(b) as being anticipated by Mizutani et al. (Virology. 2000 Sep 30;275(2):238-43).

Mizutani teaches the isolation of mouse polyA- RNA molecules from total RNA (pg. 239 col. 1, total RNA run through oligo-dT column, for example) and subsequent gel separation (fig. 1, for example). Following the logic of Applicant as presented in the specification (pg. 8-10, results w/ Saborio method; isolation of RNA from mouse), the combination of gel fractions of Mizutani containing RNA molecules greater than 300 nucleotides necessarily enhance the amplification of PrP^{Sc}.

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive.

MPEP 2113 recites, " "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a

different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)." The specification recites, "This species-specificity was not attributed to tissue-specificity because total hamster liver RNA also stimulated PrP^{sc} amplification. Thus, mice and hamsters express specific RNA molecules involved in PrP^{sc} amplification (pg. 8)." Thus, following the logic of Applicant, it would appear the mouse cells within Mizutani provided RNA molecules having the claimed characteristics and thus same structure as molecules found in mouse brain tissue.

Thus, the rejection is maintained.

Claim Rejections - 35 USC § 103 - Maintained

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Saborio et al. ("Sensitive detection of pathological prion protein by cyclic amplification of protein misfolding" Nature. 2001 Jun 14;411(6839):810-3) or Mizutani et al. (Virology. 2000 Sep 30;275(2):238-43) in view of Stratagene ("Gene Characterization Kits" 1988).

The methods of the previously applied reference(s) have been outlined in the above rejections. The previously applied reference(s) do not expressly teach kits of reagents.

Stratagene catalog provides a supportive teaching that highlights a motivation to combine reagents into kit format (pg. 39, for example).

It would have been *prima facie* obvious to a skilled artisan at the time the invention was made to combine the isolated RNA as taught by Saborio and Mizutani into a kit format as discussed by Stratagene catalog since the Stratagene catalog teaches a motivation for combining reagents of use in an assay into a kit, "Each kit provides two services: 1) a variety of different reagents have been assembled and pre-mixed specifically for a defined set of experiments. Thus one need not purchase gram quantities of 10 different reagents, each of which is needed in only microgram amounts, when beginning a series of experiments. When one considers all of the unused

chemicals that typically accumulate in weighing rooms, desiccators, and freezers, one quickly realizes that it is actually far more expensive for a small number of users to prepare most buffer solutions from the basic reagents. Stratagene provides only the quantities you will actually need, premixed and tested. In actuality, the kit format saves money and resources for everyone by dramatically reducing waste. 2) The other service provided in a kit is quality control" (pg. 39, col. 1, for example).

Response to Arguments

Applicant's arguments have been addressed in the response(s) set forth above.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher M. Babic whose telephone number is 814-880-9945. The examiner can normally be reached on Monday-Friday 10:00AM to 6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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